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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/457,173 | 12/08/1999 | JAMES D. JACOBSON | JACOB100 | 7379 |
| 7590 | 04/14/2004 | | EXAMINER | |
| BRADFORD R L PRICE BAXTER HEALTHCARE CORPORATION FENWAL DIVISION RT 120 & WILSON ROAD ROUND LAKE, IL 60073 | | | KIM, SUN U | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1723 | |

DATE MAILED: 04/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/457,173 | JACOBSON, JAMES D. | |
| | Examiner | Art Unit | |
| | John Kim | 1723 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 30 March 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-5, 14-30 and 102 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-5, 14-30 and 102 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 08 December 1999 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>3/30/04</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114.

Applicant's submission filed on 3/30/04 has been entered.

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-4, 15-18, 21-26 and 102 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,872,888 (hereinafter referred to as Ehrfeld et al.). Ehrfeld et al teach a monolithic polymeric filter membrane a polymeric filter layer (62) including micron-scale precision shaped pores (81) and a polymeric support layer (61, 63) including a precision shaped porous support structure for the filter layer wherein given example of polymer is polymethyl methacrylate (PMMA) which changes under the influence of high energy e.g., X-ray, radiation, the support layer (61, 63) is substantially coextensive with the filter layer (62), the height of the support layer is a multiple of the thickness of membrane filter layer (62), pores are connected from opposite side of a single film and pore size of the membrane filter layer (62) is 0.2 micron to 2 microns (see figures 7-9; col. 2, lines 9-38; col. 3, line 55 – col. 4, line 40).

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 5 and 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ehrfeld et al as applied to claim 1 above, and further in view of U.S. Patent No. 5,753,014 (hereinafter referred to as Van Rijn). Ehrfeld et al teach a monolithic polymer filter membrane as described in above paragraph 3. Claim 5 essentially differs from the membrane filter of Ehrfeld et al in reciting that the support layer includes at least two sublayers, a first sublayer of a selected porosity and a second layer of different porosity than the first sublayer and disposed between the first sublayer and the filter layer. Van Rijn teaches a membrane filter comprising a polymeric filter layer made of polyamide (etchable and photosensitive) including etched micron-scaled precision shaped pores of square, circular, or elongated cross section and a polymeric support layer made including multiple support layers with different pore sizes wherein the support layer is thicker than the filter layer, pore size ranges from 5 nanometers to 50 microns and filter layer is used to remove leukocytes (see figures 1, 9-15b, 25-29, 31-34; col. 1, line 57 - col. 9, line 5; col. 11, line 22 - col. 13, line 14). Van Rijn teaches a filter comprising membrane layer (46), a molecular sieve layer (50) and a support layer (45) in sequence for gas separating capability (see figure 29; col. 10, lines 23-62) and further teaches filtration membrane with three mutually connected channel with pore sizes 0.5 micron, 1.5 micron and 5 micron for sorting particles on size (see col. 10, line 63 – col. 11, line 21). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a second sublayer of different porosity disposed between the first sublayer and the filter layer in the membrane filter

of Ehrfeld et al for separating gas or sorting particles as suggested by Van Rijn. Regarding claim 27, Van Rijn teaches that the pore size of the membrane filter is between 5 nm and 50 microns (see abstract). It is well known in the art that the membrane filter with pore size less than or equal to about 0.08 microns is used in ultrafiltration application. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include membrane filter having pore size less than or equal to about 0.08 microns for ultrafiltration application.

Regarding claims 28-30, Ehrfeld et al teach that micropores are made by X-ray radiation through X-ray mask in a pattern corresponding to the distribution and cross-section configuration of micropores (see col. 3, line 67 – col. 4, line 2). Van Rijn teaches that other shapes for the cross-section of the perforation in the membrane may be chosen depending on the application including a strongly elongated or channel like shape for a potential high flow rate (see col. 8, lines 5-10) and the membrane may be used as a leucocyte filter, separating leucocytes from erythrocytes and or blood platelets (see col. 13, lines 3-6). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include an elongated cross sectional shaped pores in the membrane filter of Ehrfeld et al for application in high flow rate filtration as well as filtering leucocytes as suggested by Van Rijn.

6. Claims 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ehrfeld et al as applied to claim 1 above, and further in view of U.S. Patent No. 5,807,406 (hereinafter referred to as Brauker et al). Claims 19-20 essentially differ from the apparatus of Ehrfeld et al in reciting that polymeric material of filter layer and support layer is an etchable or photosensitive polyimide material. Ehrfeld et al teach that a membrane layer and support layer is made of polymeric material including PMMA which changes under the influence of high energy,

e.g. X-ray, radiation (see col. 3, line 51-54; col. 4, lines 34-40). Brauker et al teaches a porous microfabricated polymer membrane structure made of etchable or photosensitive polyimide (see abstract). It would have been obvious to a person of ordinary skill in the art to substitute polyimide for PMMA of Ehrfeld et al as a filter and a support layer since these materials are in a similar class of polymer and possessing characteristics of being etchable or photosensitive.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is (571) 272-1142. The examiner can normally be reached on weekdays from 7:00 AM - 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can be reached on (571) 272-1151. The fax phone number for official response is (703) 872-9306.

When sending a draft amendment by fax, please mark the paper as "DRAFT"; otherwise, mark the paper "OFFICIAL". This will expedite the processing of the paper.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0651.


John Kim
Primary Examiner
Art Unit 1723

J. Kim
April 9, 2004